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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,541	06/21/2001	Thomas J. Brennan	R-17	5815

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EXAMINER
PARAS JR, PETER

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/11/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,541	BRENNAN ET AL.	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-7,9 and 11-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8, 10, 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicant's amendment received on 6/23/03 has been entered. Claims 8 and 10 have been amended. New claims 17-19 have been added. Claims 1-19 are pending. Claims 8, 10 and 17-19 are under current consideration.

Election/Restriction

Claims 1-7, 9, 11-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Upon further consideration the following new grounds of rejection are set forth below:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-10 and 17-19 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial or a well-established utility.

The claims are directed to a transgenic mouse whose genome comprises a disruption in a target gene, wherein the target gene is capable of homologous recombination with a nucleotide sequence homologous to SEQ ID NO: 1, and

wherein the mouse exhibits increased response latency during a hot plate test and increased time in the central region during an open field test.

The instant specification has contemplated that the nucleotide sequence set forth in SEQ ID NO: 1 encodes a platelet-activating factor receptor. The instant specification has further contemplated that disruption of the nucleotide sequence set forth in SEQ ID NO: 1 in a mouse will produce a phenotype related to a platelet-activating factor receptor. The instant specification has purported that such mice may be used to identify agents that modulate or ameliorate a phenotype associated with a disruption in SEQ ID NO: 1.

The instant specification has disclosed a transgenic mouse whose genome comprises a disruption in SEQ ID NO: 1, wherein the mouse exhibits increased response latency during a hot plate test and increased time in the central region during an open field test. The claims embrace such a mouse and a method of making the mouse. The instant specification has discussed that phenotypes (increased response latency during a hot plate test and increased time in the central region during an open field test) exhibited by such a transgenic mouse could correlate to a disease or disorder. However, the evidence of record does not provide a correlation between increased response latency during a hot plate test or increased time in the central region during an open field test and any disease or disorder. Moreover, while the specification has purported that the nucleotide sequence set forth in SEQ ID NO: 1 encodes a platelet-activating factor receptor, the evidence of record has failed to provide a correlation between any platelet-activating factor receptor related disease/disorder and increased

response latency during a hot plate test or increased time in the central region during an open field test. The specification has provided general assertions that the claimed transgenic mice may be used to identify agents that affect a phenotype related to the mice.

As such, the asserted utility, for the transgenic mouse embraced by the claims, of screening agents that may affect a phenotype of said mouse as provided by the instant specification and encompassed by the claims, does not appear to be specific and substantial. The asserted utility does not appear specific and substantial to the skilled artisan since the evidence of record has not provided any suggestion of a correlation between any platelet-activating factor receptor, increased response latency during a hot plate test or increased time in the central region during an open field test, and any disease or disorder. Since the evidence of record has not provided a correlation between increased response latency during a hot plate test or increased time in the central region during an open field test and any disease or disorder, the utility of identifying agents that affect increased response latency during a hot plate test or increased time in the central region during an open field test is not apparent. The evidence of record has not provided any other utilities for the transgenic mouse embraced by the claims that are specific, substantial, and credible.

The asserted utility of the transgenic mouse embraced by the claims is based on the expectation that disrupting the nucleotide sequence set forth in SEQ ID NO: 1 would result in a detectable phenotype in the mouse. The phenotype observed in the transgenic mice embraced by the claims is increased

response latency during a hot plate test or increased time in the central region during an open field test. While the phenotypes exhibited by the claimed transgenic mouse are contemplated to be associated with a disease, the association of increased response latency during a hot plate test or increased time in the central region during an open field test with any disease has yet to be elucidated. In fact the art suggests that results obtained from behavioral studies, such as the open field and hot plate tests, are greatly influenced by the genetic background of the tested mouse. Crabbe et al (Science, 1999, Vol. 284, pages 1670-1672) observed that laboratory environment and site, test conditions, and genetic strain of a mouse can influence the results of behavioral studies. See pages 1670-1671. With regard to the open field test, Crabbe reports that A/J mice were relatively inactive, while C57BL/6 mice were very active. Crabbe further reports that on average mice tested in Edmonton were more active than those tested in Albany or Portland. See page 1671, column 1, the first full paragraph. Crabbe discusses that such inconsistencies in test results can be responsible for observed behavioral phenotypes. Given the inconsistencies in behavioral test results, Crabbe concludes by cautioning that specific behavioral effects observed in mutant (knockout) mice should be not be uncritically attributed to genetic manipulations prior to repeating testing in different laboratories using different strains of mice, if possible. See page 1672, column 1, paragraphs 2-3.

Therefore, the reference suggests a need to provide independent evidence of an association of increased response latency during a hot plate test

or increased time in the central region during an open field test with a disease or disorder. However, neither the specification nor any art of record provides evidence of the existence of a correlation between increased response latency during a hot plate test or increased time in the central region during an open field test and a disease or disorder, leaving the skilled artisan to speculate and investigate the uses of the transgenic mouse embraced by the claims. The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the transgenic mouse embraced by the claims. In light of the above, the skilled artisan would not find the asserted utility of the transgenic mouse embraced by the claims to be specific and substantial.

The following are new grounds of rejection under 35 USC § 112, 1st paragraph:

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 10, and 17-19 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

PETER PARAS
PATENT EXAMINER

Peter Paras, Jr.

Art Unit 1632